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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,219

02/14/2006

Anders Wieslander

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EXAMINER

DEAK, LESLIE R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,219	Applicant(s) WIESLANDER ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/2/07, 11/8/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 9, 10, 11, 13-25, 28-29, 31-35, 38-40, and 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,293,921 to Shinmoto et al.

In the specification and figures, Shinmoto discloses a connecting device for peritoneal dialysis. Applicant sets forth several functional limitations that describe what the apparatus does. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the applicant generally sets forth what the apparatus does, without reciting structural limitations that perform the claimed functions. As such, the Examiner has broadly interpreted the claims such that if a prior art apparatus is capable of performing the functions claimed by applicant, the claims are unpatentable over the prior art.

With regard to claims 1, 2, 28, 29, 31-34, 49, and 50, the overall setup disclosed by Shinmoto comprises a first medical device (patient side) with a patient side first connector 2. The second medical subsystem 4 comprises a bag side connector 5. Each subsystem comprises fluid that must be transferred from one subsystem to the other

(see FIGS 1A-1C, columns 7-8). The apparatus comprises a closed housing (see column 4, lines 1-4), and allow for the connection and disconnection of the medical fluid subsystems inside the housing (see column 4, lines 18-62).

With regard to claim 3, and applicant's "means for providing a substantially sterile atmosphere," the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language;
and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification.

In the specification, applicant defines the "means for providing a substantially sterile atmosphere" as a flow generator, gas source, or disinfectant member. Accordingly, the examiner is interpreting the "means for providing a substantially sterile atmosphere" to encompass a flow generator, gas source, or disinfectant member and its equivalents. Equivalent structures may include those that perform the function specified in the claim, structures that are not excluded by any specific definition provided in the specification for an equivalent, or is a structural equivalent of the corresponding element disclosed in the specification. See MPEP 2183.

Shinmoto discloses that the apparatus comprises sterilizing means for keeping the interior sterile by providing ultraviolet rays, ozone, heat, or microwaves into the interior of the housing (see column 4, lines 1-4). Since ozone is a gas, it is the position of the Examiner that Shinmoto discloses a gas source of clean gas, meeting the limitations of the claims.

With regard to claims 9, 10 14, 39, 40 Shinmoto discloses that the connection portions comprise cut-off members or caps that must be disconnected prior to fluid connection and reconnected after the connection is complete (see column 4, line 63 to column 5, line 4). As such, the mechanism is capable of performing the function claimed by Applicant.

With regard to claim 11, Shinmoto discloses that the connection apparatus comprises a housing that is opened and closed, indicating that it is capable of giving access to the connection portions when opened (See column 4, lines 18-22).

With regard to claims 13, 15, Shinmoto discloses that the connection portions are held in holders 20, 21, 22, that move relative to one another to allow the connectors to connect to one another with their shutoff members or caps (see FIGS 1A-1C and accompanying text).

With regard to claims 16-25, applicant claims several functions of the claimed apparatus. Claims 44-45 set forth steps of the method disclosed by Shinmoto. Shinmoto discloses that there are maneuvering means 2 that disconnect the connectors from their shutoff members or caps (which may be threaded), and a movable table 23 that moves the connectors along a vertical axis in linear relationship to one another (see column 4,

lines 34-62, column 7, lines 45-59). The apparatus further comprises a means to move the connectors horizontally in relationship to one another from a disconnected position to a connected position (see FIGS 1A-1C, column 7, line 24 to column 8, line 8).

With regard to claims 35 and 38, Shinmoto discloses that the apparatus comprises sterilizing means for keeping the interior sterile by providing ultraviolet rays, ozone, heat, or microwaves into the interior of the housing (see column 4, lines 1-4).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4, 8, 36, and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,293,321 to Shinmoto.

In the specification and figures, Shinmoto discloses the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 4, 8, 36, Applicant's recitation of a structure for performing the claimed function removes the claim from 35 USC § 112, 6th paragraph interpretation. However, Shinmoto discloses that ozone or ultraviolet rays may be provided in the housing in order to sterilize the apparatus (see column 4, lines 1-4). As such Shinmoto suggests the channel (since gas cannot flow without some sort of channel) and disinfecting member claimed by applicant.

With regard to claims 41-43, Shinmoto discloses that the apparatus comprises connectors mounted in the receivers in the container. Since such connectors cannot be placed without opening the container, Shinmoto reasonably suggests the steps of opening the container, placing the connectors, and then closing the container before beginning the connection operation disclosed by Shinmoto.

5. Claims 5-7 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,293,321 to Shinmoto et al in view of US 4,738,668 to Bellotti et al.

In the specification and figures, Shinmoto discloses the apparatus substantially as claimed by applicant (see rejection above). Shinmoto does not disclose that the apparatus comprises a filter and flow generator that push a sterilizing gas to the interior of the connecting apparatus. Bellotti discloses a sterile connection apparatus with an ampoule 40 in fluid connection with the connector 18. A chemical reaction in the ampoule forces a sterilizing gas into the connector 18 through filter 38 creating an overpressure to drive out unsterile gas (see column 6, lines 43-68). Since all the elements are known in the art, it would have been obvious for one of ordinary skill in the art to combine the known elements according to known methods to yield the predictable result of a sterile connection apparatus with a gas flow generator with a filter to sterilize the connector.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,293,321 to Shinmoto et al in view of US 4,882,496 to Bellotti et al

In the specification and figures, Shinmoto discloses the apparatus substantially as claimed by applicant (see rejection above). Shinmoto does not disclose that the

container comprises a base and a cover. However, Bellotti discloses a patient connector apparatus comprising a base 14 that holds connectors, enclosed by lid 12 in order to provide a sterile location for connecting the fluid lines (see FIG2, generally, column 4). Therefore, it would have been obvious at the time of invention to place the automatic connector apparatus disclosed by Shinmoto in an enclosure as disclosed by Bellotti in order to enclose the connectors in a sterile space, as taught by Bellotti.

7. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,293,321 to Shinmoto et al in view of US 4,655,573 to Bellotti et al.

In the specification and figures, Shinmoto discloses the apparatus substantially as claimed by applicant (see rejection above). With regard to claims 26 and 27, Shinmoto does not disclose that any of the maneuvering members comprises a user-actuated grip portion. However, Bellotti discloses an aseptic tube connection apparatus that comprises an external handle 64 that is rotated by a user to engage gears inside the closed apparatus to move fluid connections in and out of communication with one another (see column 4, lines 41-50). Since all the elements are known in the art, it would have been obvious for one of ordinary skill in the art to combine the known elements according to known methods to yield the predictable result of a sterile connection apparatus with a manually actuated handle to move the connections into their respective places.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
10 April 2008